

(c) By regulation promulgated under this section, the Commissioner may change the classification from class III into:

(1) Class II if the Commissioner determines that special controls in addition to general controls would provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls to provide assurance; or

(2) Class I if the Commissioner determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

(d) The rulemaking procedures in § 10.40 of this chapter apply to proceedings to reclassify a device under section 513(e), except that the Commissioner may secure a recommendation with respect to a proposed reclassification from the classification panel to which the device was last referred. The panel will consider a proposed reclassification submitted to it by the Commissioner in accordance with the consultation procedures of § 860.125. Any recommendation submitted to the Commissioner by the panel will be published in the FEDERAL REGISTER when the Commissioner promulgates a regulation under this section.

(e) Within 180 days after the filing of a petition for reclassification under this section, the Commissioner, by order published in the FEDERAL REGISTER, will either deny the petition or give notice of his intent to initiate a change in the classification of the device.

(f) If a device is reclassified under this section, the regulation effecting the reclassification may revoke any special control or premarket approval requirement that previously applied to the device but that is no longer applicable because of the change in classification.

(g) A regulation under this section changing the classification of a device from class III to class II may provide that such classification will not take effect until the effective date of a special control for the device established under section 514 of the act.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992]

§ 860.132 Procedures when the Commissioner initiates a performance standard or premarket approval proceeding under section 514(b) or 515(b) of the act.

(a) Sections 514(b) and 515(b) of the act require the Commissioner to provide, by notice in the FEDERAL REGISTER, an opportunity for interested parties to request a change in the classification of a device based upon new information relevant to its classification when the Commissioner initiates a proceeding either to develop a performance standard for the device if in class II, or to promulgate a regulation requiring premarket approval for the device if in class III. In either case, if the Commissioner agrees that the new information warrants a change in classification, the Commissioner will publish in the FEDERAL REGISTER notice of the Commissioner's intent to initiate a proceeding under section 513(e) of the act and § 860.130 to effect such a change.

(b) The procedures for effecting a change in classification under sections 514(b) and 515(b) of the act are as follows:

(1) Within 15 days after publication of the Commissioner's notice referred to in paragraph (a) of this section, an interested person files a petition for reclassification in accordance with § 860.123.

(2) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.

(3) Within 60 days after publication of the notice referred to in paragraph (a) of this section, the Commissioner, by order published in the FEDERAL REGISTER, either denies the petition or gives notice of his intent to initiate a change in classification in accordance with § 860.130.

§ 860.134 Procedures for “new devices” under section 513(f) of the act and reclassification of certain devices.

(a) Section 513(f)(2) of the act applies to proceedings for reclassification of a device currently in class III by operation of section 513(f)(1) of the act. This category includes any device that is to be first introduced or delivered for introduction into interstate commerce